

ENVIRONMENTAL PROTECTION AGENCY

OPTS-41028; FRL-3292-3 I

Twenty-First Report of the Interagency Testing Committee to the Administrator; Receipt of Report and Request for Comments Regarding Priority List of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Interagency Testing Committee (ITC), established under section 4(e) of the Toxic Substances Control Act (TSCA), transmitted its Twenty-First Report to the Administrator of EPA on October 30, 1987. This report, which revises and updates the Committee's priority list of chemicals, adds six chemicals to the list for priority consideration by EPA in the promulgation of test rules under section 4(a) of the Act. The new chemicals are Acid Blue 40, Acid form of Acid Blue 40, Acid Blue 45, Acid form of Acid Blue 45, Disperse Blue 56 and Disperse Red 60. These chemicals are not designated for response within 12 months. The Twenty-First Report is included in this notice. The Agency invites interested persons to submit written comments on the Report, and to attend a Focus meeting to help narrow and focus the issues raised by the ITC's recommendations. Members of the public are also invited to inform EPA if they wish to be notified of subsequent public meetings on these chemicals. ITC also notes the removal of three chemicals from the priority list because EPA has responded to the ITC's Previous recommendations for testing of the chemicals.

DATES: Written comments should be submitted by December 21, 1987. A Focus Meeting on the six new chemicals will be held on December 15, 1987.

ADDRESS: Send written submission to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE G-004, 401 M St., SW., Washington, DC 20460.

Submissions should bear the document control number (OPTS-41028).

The public record supporting this action, including comments, is available for public inspection in Rm. NE G-004 at the address noted above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Focus Meeting will be held at EPA Headquarters, Rm. 103 NE Mall, 402 M St., SW., Washington, DC. Persons planning to attend the

Focus Meeting and/or seeking to be informed of subsequent public meetings on these chemicals, should notify the TSCA Assistance Office at the address listed below. To ensure seating accommodations at the Focus Meeting, persons interested in attending are asked to notify EPA at least one week ahead of the scheduled date.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. (202-554-1404).

SUPPLEMENTARY INFORMATION: EPA has received the Report of the TSCA Interagency Testing Committee to the Administrator.

I. Background

TSCA (Pub. L. 94-469, 90 Stat. 2003 et seq.; 15 U.S.C. 2601 et seq.) authorizes the Administrator of EPA to promulgate regulations under section 4(a) requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemical substances and mixtures may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee to make recommendations to the Administrator of EPA on chemical substances and mixtures to be given priority consideration in proposing test rules under section 4(a). Section 4(e) directs the Committee to revise its list of recommendations at least every 6 months as necessary. The ITC may "designate" up to 50 substances and mixtures at any one time for priority consideration by the Agency. For such designations, the Agency must within 12 months either initiate rulemaking or issue in the Federal Register its reasons for not doing so. The ITC's Twenty-First Report was received by the Administrator on October 30, 1987, and follows this Notice. The Report adds six substances to the TSCA section 4(e) priority list.

II. Written and Oral Comments and Public Meetings

EPA invites interested persons to submit detailed comments on the ITC's new recommendations. The Agency is interested in receiving information concerning additional or ongoing health and safety studies on the subject chemicals as well as information relating to the human and environmental exposure to these chemicals. A notice is published elsewhere in today's **Federal**

Register adding the substances recommended in the ITC's Twenty-First Report to the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716). The section 8(d) rule requires the reporting of unpublished health and safety studies on the listed chemicals. These chemicals will also be added to the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712) published elsewhere in this issue. The section 8(a) rule requires the reporting of production volume, use, exposure, and release information on the listed chemicals.

A Focus Meeting will be held to discuss relevant issues pertaining to these chemicals and to narrow the range of issues/effects which will be the focus of the Agency's subsequent activities in responding to the ITC recommendations. The **Focus** Meeting will be held on December 15, 1987 at 1 p.m. at EPA Headquarters, Rm. 103 NE Mall, 401 M St., SW., Washington, DC. This meeting is intended to supplement and expand upon written comments submitted in response to this notice.

Persons wishing to attend this meeting or subsequent meetings on these chemicals should call the TSCA Assistance Office at the telephone number listed above at least one week in advance.

All written submissions should bear the identifying docket number (OPTS-41028).

III. Status of List

In addition to adding the six recommendations to the priority list, the ITC's Twenty-First Report notes the removal of three chemicals from the list since the last ITC report because EPA has responded to the Committee's prior recommendations for testing of the chemicals. Subsequent to ITC's preparation of its Twentieth Report, EPA responded to the ITC's recommendations for three additional chemicals. The three chemicals removed and the dates of publication in the Federal Register of EPA's responses to the ITC for these chemicals are: Cyclohexane, May 20, 1987 (52 FR 19096); 2,6-di-*tert*-butylphenol, June 25, 1987 (52 FR 23862); and 3,4-dichlorobenzotrifluoride, June 23, 1987 (52 FR 23547).

The current list contains three designated substances, one chemical recommended with intent-to-designate and 12 recommended substances.

Authority: 15 U.S.C. 2603.

Dated: M
J. Merenda
Director, E
Division. C

Summary

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Dated: November 12, 1987.

J. Merenda,
Director, Existing Chemical Assessment
Division, Office of Toxic Substances.

Summary

Section 4 of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469) provides for the testing of chemicals in commerce that may present an unreasonable risk of injury to health or the environment. It also provides for the establishment of a Committee (ITC), composed of representatives from eight designated Federal agencies, to recommend chemical substances and mixtures (chemicals) to which the Administrator of the U.S. Environmental Protection Agency (EPA) should give priority consideration for the promulgation of testing rules.

Section 4(e)(1)(A) of TSCA directs the Committee to recommend to the EPA Administrator chemicals to which the Administrator should give priority consideration for the promulgation of testing rules pursuant to section 4(a). The Committee is required to designate those chemicals, from among its recommendations, to which the Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. At least every 6 months, the Committee makes those revisions in the TSCA section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

As a result of its deliberations, the Committee is revising the TSCA section 4(e) Priority List by the addition of six chemicals.

The Priority List is divided into three parts: Part A contains those recommended chemicals and groups designated for priority consideration and response by the EPA Administrator within 12 months. Part B contains chemicals and groups of chemicals recommended with intent-to-designate. This category was established by the Committee in its seventeenth report (50 FR 47603; November 19, 1985) to take advantage of rules promulgating automatic reporting requirements for non-designated ITC recommendations under the section 8(a) Preliminary Assessment rule and the TSCA section 8(d) Health and Safety Data Reporting rule. Information received following recommendation with intent-to-designate may influence the Committee to either designate or not designate the chemicals or groups of chemicals in a subsequent report to the Administrator. Part C contains chemicals and groups of

chemicals that have been recommended for priority consideration by EPA without being designated for response within 12 months. The changes to the Priority List are presented, together with the types of testing recommended, in the following Table 1:

TABLE 1.—ADDITIONS TO THE SECTION (e) PRIORITY LIST, NOVEMBER 1987

Chemical/Group	Recommended studies
A. Designated for response within 12 months:	
None.	
B. Recommended with Intent-to-Designate:	
None.	
C. Recommended Without Being Designated for Response Within 12 Months:	
Acid Blue 40 ¹ (CAS No. 6424-k-7). Acid form of Acid Blue 40 ² (CAS No. 6247-34-3). Acid Blue 45 ³ (CAS No. 2861-02-1). Acid form of Acid Blue 45 ⁴ (CAS No. 128-86-9). Disperse Blue 56 ⁵ (CAS No. 12217-79-7). Disperse Red 60 ⁶ (CAS No. 17418-58-5).	Health Effects: Genotoxicity for each of the six dyes. Chemical Fate: None. Ecological Effects: None.

CA Index Names (9CI).
¹ 2-Anthracenesulfonic acid, 4-[(4-(acetylamino)phenyl)amino]-1-amino-9,10-dihydro-9,10-dioxo-, monosodium salt.
² 2-Anthracenesulfonic acid, 4-[(4-(acetylamino)phenyl)amino]-1-amino-9,10-dihydro-9,10-dioxo-
³ 2,6-Anthracenedisulfonic acid, 4,8-diamino-9,10-dihydro-1,5-dihydroxy-9,10-dioxo-, disodium salt.
⁴ 2,6-Anthracenedisulfonic acid, 4,8-diamino-9,10-dihydro-1,5-dihydroxy-9,10-dioxo-
⁵ 9,10-Anthracenedione, 1,5-diaminochloro-4,8-dihydroxy-
⁶ 9,10-Anthracenedione, 1-amino-4-hydroxy-2-phenoxy-

TSCA Interagency Testing Committee Statutory Member Agencies and Their Representatives

Council on Environmental Quality
Carroll Curtis, Member
Department of Commerce
Patrick D. Cosslett, Member
Raimundo Prat, Alternate
Environmental Protection Agency
John D. Walker, Member and Vice
Chairperson
Laurence S. Rosenstein, Alternate
National Cancer Institute
Richard Adamson, Member
Elizabeth K. Weishurper, Alternate
National Institute of Environmental
Health Sciences
James K. Selkirk, Member and

Chairperson
National Institute for Occupational
Safety and Health
Bryan D. Hardin, Member
Rodger L. Tatken, Alternate
National Science Foundation
Rodger W. Baier, Member
Jarvis L. Moyers, Alternate
Occupational Safety and Health
Administration
Stephen Mallinger, Alternate

Liaison Agencies and Their Representatives

Consumer Product Safety Commission
Lakshmi C. Mishra
Department of Agriculture
Richard M. Parry, Jr.
Elise A. B. Brown.
Department of Defense
Vacant
Department of The Interior
Sarah Gerould¹
Food and Drug Administration
Arnold Borsetti
National Library of Medicine
Vera Hudson
National Toxicology Program
Dorothy Canter

Committee Staff

Robert I. Brink, Executive Secretary
Norma Williams, ITC Coordinator

Support Staff

Alan Carpien-Office of the General
Counsel, EPA

Notes

The Committee acknowledges and is grateful for the assistance and support given the ITC by the staff of Dynamac Corporation (technical support contractor) and personnel of the EPA Office of Toxic Substances.

Chapter & Introduction

1.1 Background. The TSCA Interagency Testing Committee (Committee) was established under section 4(e) of the Toxic Substances Control Act of 1976 (TSCA, Pub. L. 94-469). The specific mandate of the Committee is to recommend to the Administrator of the U.S. Environmental Protection Agency (EPA) chemical substances and mixtures in commerce that should be given priority consideration for the promulgation of testing rules to determine their potential hazard to human health and/or the environment. TSCA specifies that the Committee's recommendations shall be in the form of the Priority List, which is to be published in the Federal Register. The Committee is directed by section

¹ Appointed on June 10, 1987.

4(e)(1)(A) of the TSCA to designate those chemicals on the Priority List to which the EPA Administrator should respond within 12 months by either initiating a rulemaking proceeding under section 4(a) or publishing the Administrator's reason for not initiating such a proceeding. There is no statutory time limit for EPA response regarding chemicals that ITC has recommended but not designated for response within 12 months.

At least every 6 months, the Committee makes those revisions in the section 4(e) Priority List that it determines to be necessary and transmits them to the EPA Administrator.

The Committee is composed of representatives from eight statutory member agencies and seven liaison agencies. The specific representatives and their affiliations are named in the front of this report. The Committee's chemical review procedures and priority recommendations are described in previous reports (Refs. 1 through 5).

1.2 Committee's previous reports. Twenty previous reports to the EPA Administrator have been issued by the Committee and published in the **Federal Register** (Refs. 1 through 5). Ninety-six entries (chemicals and groups of chemicals) were recommended for priority consideration by the EPA Administrator and designated for response within 12 months. In addition, eight chemicals and one group of chemicals were recommended without being so designated.

1.3 Committee's activities during this reporting period. Between April 18, 1987 and October 15, 1987, the Committee continued to review chemicals from its fourth and fifth scoring exercises, and from nominations by Member Agencies, Liaison Agencies and State Agencies. The Committee also began reviewing chemicals from its sixth scoring exercise, which was completed in **January 1987**.

The Committee contacted chemical manufacturers and trade associations to request information that would be of value in its deliberations. Most of those contacted provided unpublished information on current production, exposure, uses, and effects of chemicals under study by the Committee.

During this reporting period, the Committee reviewed available information on 56 chemicals. Six were selected for addition to the section 4(e) Priority List, and thirty-one were deferred indefinitely. The remaining chemicals are still under study.

In its twentieth report to the EPA Administrator (Ref. 5, ITC, 1987), the

Committee placed ethylbenzene (CAS No. 100-41-4) on the Priority List in the "Recommended with Intent-to-Designate" category. The Committee recommended that ethylbenzene be tested for acute toxicity to freshwater algae and invertebrates and to saltwater algae, invertebrates and fish. Subsequently, the Committee learned that acute toxicity testing of ethylbenzene with freshwater invertebrates has recently been completed at the University of Wisconsin. The Committee also has been informed (Ref. 6, SOCMA, 1987) that a consortium of ethylbenzene producers, the Styrene and Ethylbenzene Association, voluntarily has sponsored studies on the other acute toxicity tests recommended by the Committee. The Committee has deferred a decision on whether or not to designate ethylbenzene pending a review of the data developed during the above studies.

1.4 The TSCA section 4(e) Priority List. Section 4(e)(1)(B) of TSCA directs the Committee to: "... make such revisions in the [priority] list as it determines to be necessary and ... transmit them to the Administrator together with the Committee's reasons for the revisions." Under this authority, the Committee is revising the Priority List by adding six chemicals: Acid Blue 40 and its related acid form, Acid Blue 45 and its related acid form, Disperse Blue 58 and Disperse Red 60. Three chemicals are being removed from the Priority List at this time. Cyclohexane (CAS No. 110-28-7) and 2,6-di-tert-butylphenol (CAS No. 128-39-2) were subjects of Notices of Proposed Rulemaking (52 FR 19096; May 20, 1987 and 52 FR 23862; June 25, 1987 respectively) and 3,4-dichlorobenzotrifluoride (CAS No. 328-84-7) which was the subject of a Testing Consent Order (52 FR 23547; June 23, 1987).

With the six new recommendations and three removals noted in this report, sixteen entries now appear on the section 4(e) Priority List. The Priority List is divided in the following Table 2 into three parts: namely, A. Chemicals and Groups of Chemicals Designated for Response Within 12 Months, B. Chemicals and Groups of Chemicals Recommended with Intent-to-Designate, and C. Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months. Table 2 follows:

TABLE 2-THE TSCA SECTION 4(e) PRIORITY LIST [November 1987]

Entry	Date of designation
A. Chemicals and Groups of Chemicals Recommended and Designated for Response Within 12 Months:	
1. Tributyl phosphate	Nov. 1986.
2. Isopropanol	May 1987.
3. Methyl tert-butyl ether	May 1987.
Entry	Date of recommendation
B. Chemicals and Groups of Chemicals Recommended with Intent-to-Designate:	
1. Ethylbenzene	May 1987.
C. Chemicals and Groups of Chemicals Recommended Without Being Designated for Response Within 12 Months:	
1. Diisodecyl phenyl phosphite .	Nov. 1985.
2. C.I. Disperse Blue 79.....	Nov. 1986.
3. Methyl ethyl ketoxime.....	Nov. 1986.
4. N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[[2-bromo-4,6-dinitrophenyl]azo]-4-methoxy phenyl]-acetamide.	May 1987.
5. N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[2-chloro-4,6-(dinitrophenyl)azo]-4-methoxy phenyl]-acetamide.	May 1987.
6. N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[[2-chloro-4,6-dinitrophenyl]azo]-4-ethoxy phenyl]-acetamide.	Nov. 1987.
7. Acid Blue 40	Nov. 1987.
8. 2-Anthracenesulfonic acid, 4-[(4-(acetylamino)phenyl)amino]-1-amino-9,10-dihydro-9,10-dioxo-	Nov. 1987.
9. Acid Blue 45	Nov. 1987.
10. 2,6-Anthracenedisulfonic acid, 4,8-diamino-9,10-dihydro-1,5-dihydroxy-9,10-dioxo-	Nov. 1987.
11. Disperse Blue 56.....	Nov. 1987.
12. Disperse Red 60.....	Nov. 1987.

References

- (1) Sixteenth Report of the TSCA Interagency Testing Committee to the Administrator. Environmental Protection Agency. TSCA Interagency Testing Committee. May 21, 1985. 50 FR 20930-20939. Includes references to Reports 1 through 15 and an annotative list of removals.
- (2) Seventeenth Report of the TSCA Interagency Testing Committee to the Administrator. Environmental Protection

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Agency. TSCA Interagency Testing Committee. November 19, 1985, 50 FR 47603-47612.

(3) Eighteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 19, 1986, 51 FR 18368-18375.

(4) Nineteenth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee. November 14, 1986, 51 FR 41417-41432.

(5) Twentieth Report of the TSCA Interagency Testing Committee to the Administrator, Environmental Protection Agency. TSCA Interagency Testing Committee, May 20, 1987, 52 FR 19020-19026.

(6) SOCMA. Letter of October 14, 1987, from Eric A. Clarke, Executive Director of the Styrene and Ethylbenzene Association. Synthetic Organic Chemical Manufacturers

Association, Inc., to R. Brink, Executive Secretary, Interagency Testing Committee.

Chapter 2—Recommendations of the Committee

2.1 *Chemicals recommended for priority consideration by the EPA Administrator.* As provided by section 4(e)(1)(B) of TSCA, the Committee is adding the following chemical substances to the section 4(e) Priority List: Acid Blue 40 and its related acid form, Acid Blue 45 and its related acid form, Disperse Blue 56 and Disperse Red 60. The recommendation of these chemicals is being made after considering the factors identified in section 4(e)(1)(A) and other relevant information, as well as the professional judgment of Committee members.

2.2 *Chemicals designated for response within 12 months.* None.

2.3 *Chemicals recommended with intent-to-designate.* None.

2.4 *Chemicals recommended without being designated for response within 12 months—Summary of recommended studies.* It is recommended that selected aminoanthraquinone dyes be tested for the following:

1. *Chemical fate:* None.

2. *Health effects:* Acid Blue 40 and its related acid for genotoxicity.

Acid Blue 45 and its related acid for genotoxicity.

Disperse Blue 56 for genotoxicity.

Disperse Red 60 for genotoxicity.

3. *Ecological effects:* None.

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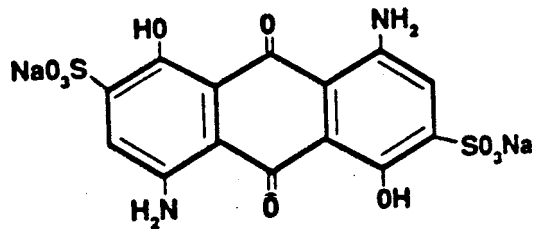
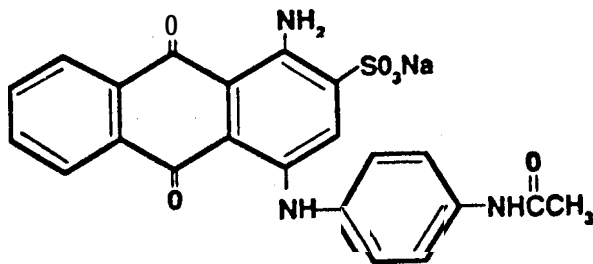
Physical and Chemical Information ^{1,2}_{a,b/}Acid Blue 40
C.I. 62125Acid Blue 45
C.I. 63010

CAS No.

6424-85-7

2861-02-1

Synonyms

2-Anthracenesulfonic acid, 4-[(4-(acetylamino) phenyl) amino]-1-amino-9,10-dihydro-9,10-dioxo-, monosodium salt (9CI)**2,6-Anthracenedisulfonic acid, 4,8-diamino-9,10-dihydro-1,5-dihydroxy-9,10-dioxo-, disodium salt (9CI)**Structural
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Description
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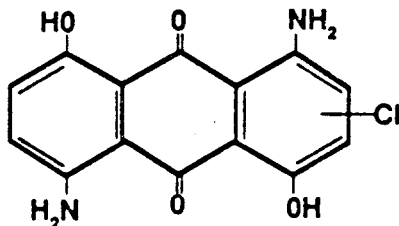
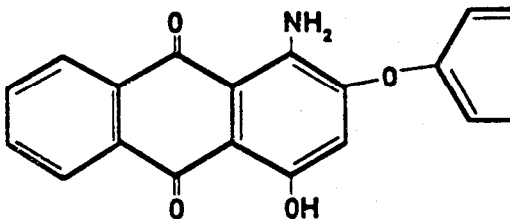
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Physical and Chemical Information ^{1,2}

	Disperse Blue 56 C.I. 63285	Disperse Red 60 C.E. 60754
CAS No.	12217-79-7	17418-58-5
Synonyms	9,10-Anthracenedione 1,5-diaminochloro-4,8-dihydroxy- (9CI)	9,10-Anthracenedione, 1-amino-4-hydroxy-2-phenoxy- (9CI)
Structural Formula		
Empirical Formula	C ₁₄ H ₉ ClN ₂ O ₄	C ₂₀ H ₁₃ NO ₄
Molecular Weight	305	331
Description of Chemical	--	Deep red powder ^{1,2}

^{1,2} Colour Index (1971, Ref. 6), unless specified otherwise.

^{1,2} No quantitative information was found for melting point, boiling vapor pressure, solubility in water and log octanol/water partition coefficient values. In general, acid dyes are water soluble and disperse dyes are only slightly soluble in water (Ref. 6, Colour Index, 1971).

^{1,2} Palanil Red BF, a proprietary mixture containing C.I. Disperse Red 60 composition unspecified (Ref. 1, BASF, 1986).

Rationale for Recommendations

I. Introduction

The Committee has systematically reviewed the entire category of aminoanthraquinone dyes, which includes 338 compounds identified in the Colour index (1971, Ref. 6). At least ninety percent of the 338 compounds are not produced or imported in commercially significant amounts in the United States. Of thirty to forty commercially important aminoanthraquinone dyes, human health effects concerns focused primarily on the aminoanthraquinone dyes with a primary amino group ($-\text{NH}_2$). Ecological fate and effects concerns were directed toward the non-symmetrical aminoanthraquinone dyes with (1) an ethanolamino group, or (2) cationic nitrogen, or (3) an electron-releasing group (e.g., $-\text{NH}_2$, $-\text{NHR}$, $-\text{OH}$) in the 1,4 positions. As a result of these reviews, the Committee has concluded that Acid Blue 40, Acid Blue 45, Disperse Blue 56 and Disperse Red 60 should be tested for genotoxicity. Acid Blue 40 and Acid Blue 45, which are monosodium and disodium salts, respectively, may be used interchangeably with their acid forms. Therefore, the Committee is including the related acid forms in its recommendation. These dyes (and/or the acid forms of Acid Blue 40 and Acid Blue 45) are believed to be among the commercially more important of the primary aminoanthraquinone dyes. Although testing is being recommended for only four of the aminoanthraquinones (and/or the analogous acid forms of Acid Blue 40 and Acid Blue 45), the Committee believes it is appropriate to consider these four dyes as representative of other aminoanthraquinone dyes that, in aggregate, are commercially important and used in appreciable amounts annually.

II. Exposure Information

A. Production/Use

Annual production and importation volumes, from 1979 through 1982, for the recommended dyes exceeded 3 million pounds (Ref. 20, Sigman et al., 1985).

The main uses of the aminoanthraquinone dyes are to color both natural and synthetic fibers (Ref. 6, Colour Index, 1971). Some of the dyes also have non-textile applications. For example, Acid Blue 40 is also used to color leather and paper (Ref. 5, Colour Index, 1971.) Acid Blue 45 is used as a colorant in inks, paper, anodized aluminum, plastics, soap, cosmetics, and leather (Ref. 6, Colour Index, 1971).

B. Evidence for Human Exposure

As many as 1,450 workers may be exposed to the individual dyes (Ref. 13, NIOSH, 1984). OSHA has not set exposure limits for these dyes, but BASF (1986, Ref. 1) established an internal exposure limit of $5 \text{ mg}/\text{m}^3$ for Disperse Red 60, and Ciba-Geigy (1985, Ref. 5) recommends a short-term limit of $10 \text{ mg}/\text{m}^3$ for the petroleum hydrocarbons used in a mixture containing this dye.

C. Environmental Release

It has been estimated that about 10 percent of textile dyes are released to the environment (Ref. 16, Porter, 1973) in waste streams, with the potential for entering rivers or other water courses.

III. Chemical Fate Information

The Committee has evaluated available chemical fate information on aminoanthraquinone dyes. The limited data available indicate that aminoanthraquinone dyes are relatively persistent in the environment but are unlikely to be found at concentrations that will cause adverse ecological effects. Therefore, no chemical fate studies are being recommended at this time.

IV. Biological Effects of Concern to Human Health

A. Metabolism and Toxicokinetics

Absorption of Disperse Red 60 occurred in rats following oral dosing (Ref. 12, Leist, 1982). Aminoanthraquinones are acylated to acetyl or formyl derivatives or hydroxylated on one of the aromatic rings (Ref. 19, Sigman et al., 1983).

Acid Blue 45 had no effect on ADP uptake (Ref. 2, Boos and Schlimme, 1981). The parent compound 2-aminoanthraquinone, when fed to female F-344 rats, increased liver cytochrome P-450, NADPA-cytochrome-c-reductase, BP hydroxyase, epoxide hydrolase, and 1-naphthol-O-glucuronyl transferase as well as N-demethylases, aniline hydroxylase, and azo dye reductase enzymes (Ref. 11, Rarnanathan et al., 1981).

B. Acute and Subchronic (Short-Term) Effects

The acute oral toxicity (LD_{50}) of both Acid Blue 40 and Disperse Red 60 in rats is reported to be greater than $5,000 \text{ mg}/\text{kg}$ (Ref. 7, American Hoechst, undated, as cited in ETAD, 1987; Ref. 12, Leist, 1982). In rats, the acute oral LD_{50} of Palanil Red BF, a proprietary mixture containing an unspecified amount of Disperse Red 60, was reported to be greater than $6,400 \text{ mg}/\text{kg}$ (Ref. 1, BASF, 1986).

Dispersé Red 60 had a very low cumulative toxicity in rats [Ref. 12, Leist, 1982].

C. Genotoxicity

No information was found regarding the genotoxicity of the selected dyes. However, genotoxicity data are available for other aminoanthraquinone dyes. For example, Disperse Blue 1 was positive in two separate studies in *Salmonella typhimurium* (Ref. 4, Brown and Brown, 1976; Ref. 15, NTP, 1986b) but negative in CHO cells (Ref. 15, NTP, 1986b). Disperse Violet 1 was positive in *S. typhimurium* in three of five experiments (Ref. 4, Brown and Brown, 1976; Ref. 22, Tamaro et al., 1975; Ref. 23, Yoshikawa et al., 1976; Ref. 8, Henry, 1983; Ref. 18, Shahin and Von Borstel, 1978). This dye tested positively in a DNA repair test (Ref. 4, Brown and Brown, 1976) and in *E. coli* (Ref. 11, Kvelland, 1983) but was negative in *S. cerevisiae* (Ref. 18, Shahin and Von Borstel, 1978). Disperse Violet 8 was positive in *S. typhimurium* but negative in a DNA repair test in the same strain (Ref. 4, Brown and Brown, 1976). Reactive Blue 19 was negative in *S. typhimurium* (Ref. 4, Brown and Brown, 1976). Genotoxicity tests have been done on Disperse Red 4 and 15 and on Solvent Red 1, using the Ames *Salmonella* assay. Disperse Red 4 was nonmutagenic in all five test strains used (Ref. 3, Brown, 1980). Disperse Red 15 was mutagenic only in strain TA1537, with and without metabolic activation (Ref. 4, Brown and Brown, 1976). A mutagenic response was observed in one of two studies conducted with Solvent Red 1, although a dose response relationship was not apparent (Ref. 8, Henry, 1983).

D. Oncogenicity

No information was found regarding the oncogenicity of the selected dyes. However, limited data are available on other aminoanthraquinone dyes. Feeding Disperse Blue 1 led to development of bladder neoplasms and other tumors in male and female rats, but mice were affected only marginally (Ref. 14, NTP, 1986a). Prolonged skin application of Disperse Violet 8 led to tumor formation in rats (Ref. 10, Kuz'menko and Petrovskaya, 1981). A test of Reactive Blue 19 was not adequate (Ref. 19, Pliss, 1967, as cited in Sigman et al., 1983).

E. Reproductive and Developmental Effects

No information was found.

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F. Chronic (Long-Term) Effects

No information was found.

G. Observations in Humans

No information was found regarding the selected dyes. However, Disperse Blue 1 and Disperse Violet 8 were noted to cause positive sensitization in humans (Ref. 21, Sim-Davies, 1972; Ref. 9, Kuz'menko, 1983).

H. Rationale For Health Effects Recommendations

The aminoanthraquinone dyes are used mostly to dye fibers. The volume of each dye and the number of workers exposed vary each year, depending on the colors in style. In order to obtain some measure of their biological effects, genotoxicity studies should be done on the recommended dyes.

Further genotoxicity studies on the aminoanthraquinone dyes reported to be mutagenic in Section IV.C are not being recommended at this time because of the presumed low human exposure potentials of these compounds.

V. Ecological Effects of Concern

The Committee has evaluated available ecological effects information on aminoanthraquinone dyes. The available evidence indicates that these dyes are unlikely to be present in the environment at concentrations that cause adverse effects. Therefore, no ecological effects studies are being recommended at this time.

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